

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K962370

1. Name and Address

This Summary of Safety and Effectiveness is being submitted by Challenge Products, Inc., Lake Road 54-22 P.O. Box 468, Osage Beach, Missouri 65065.

2. Name of the Device

The device is generally known as a prophylaxis paste.

3. Identification of Predicate Device(s)

Challenge Products, Inc. Prophylaxis Paste, FDA control number K940496.

4. Description of the Device

The device is a prophylaxis paste which is used by dental professionals to help remove resistant stains from the surface of the teeth.

5. Intended Use of the Device

The intended use of the prophylaxis paste is to help remove materia alba, plaque and resistant stains from the teeth.

6. Comparison of Technological Characteristics

The differences between Challenge's new prophylaxis paste and the predicate device are minor and do not impact the safety and effectiveness of the device in any significant way.

7. Safety

Challenge reviewed the 11 MDR records filed with CDRH relating to FDA's product code, "EJR" which were obtained from a CD-ROM database¹. Most of the events occurred as a result from an allergic or adverse reaction to a prophylaxis paste.

¹ The Medical Device Library, IHS Regulatory Products, 15 Inverness Way East, Englewood, CO 80150.

jet powder. 3 of the 11 reports were filed for a prophylactic paste and 1 report was on a patient with a history of allergies. These reports follow.